

# GX



**FAST AND ACCURATE READINGS OF URINE ANALYSIS AND IMMUNO DIAGNOSTIC CARTRIDGES AT AN AFFORDABLE COST**

## THE CHALLENGE

Provide a solution to address the problems of inaccuracies in visual reading of urine analysis and immuno diagnostic cartridges, and maintaining accurate patient records.

## THE SOLUTION

Following an extensive feasibility study conducted by GX Design Engineers, we responded with the creation of the Clinitek Status. A novel arrangement of multiple wavelength LEDs are combined with plastic lenses, light guides and a CCD array. These provide elements of spectrometry and reflectometry, which make this instrument capable of giving fast and accurate readings at a vastly reduced cost.

## THE RESULT

The Clinitek Status has set the industry standard and is currently on sale in over 100 countries.

## QUICK FACTS

FDA APPROVAL

TOUCH SCREEN

LOW COST MANUFACTURING

CCD TECHNOLOGY

UK MANUFACTURE

PATENTED

## TECHNICAL DATA

### ELECTRONICS

Our design team developed a low-cost microcontroller-based motherboard to interface to the instrument hardware, including the optoelectronics emitters & sensors at the core of the instrument as well as the drawer, motor, and printer; the same microcontroller was also used to provide the user interface by driving the main LCD display and monitoring user input from buttons and touchscreen.

### SOFTWARE

Our software team first developed software to run on the early testbed units to capture characteristic data which was used to produce the proprietary diagnostic algorithms. The team then incorporated these algorithms, together with a friendly user interface, into prototype instruments which were used for clinical trials, life testing, and compliance testing.

### MECHANICAL & INDUSTRIAL DESIGN

The initial brief was very simple - to develop a low cost strip reader! Many



PRODUCT DESIGN



VALUE ENGINEERING



CONTROL SYSTEM DEVELOPMENT

different designs were created in 3D CAD format and a combination of animations and physical models used to evaluate each of the design proposals. After considering the options a design was chosen to develop into an IWM and 50 units were built for field testing and focus group studies.

This focus group feedback and market analysis led to the introduction of a motorised loading table and a large touch screen. This actually increased manufacturing costs but the instrument remained highly competitive. The entire product was redesigned against a detailed specification that came out of the initial stages of work. The Bayer corporate design philosophy was applied to the new product. Five block appearance models were designed and made for focus groups to evaluate. The distinctive 'wing' design emerged as the eventual direction and GX Design Engineers then completed the industrial and detail design work including 3D CAD data and FEA analysis plus the electronic software and hardware design. These final stages of the product design were carried out working with Bayer manufacturing at their recently acquired Sudbury plant.

Throughout the project GX Design Engineers worked with Bayer engineers and chemists. FMEA analysis was carried out continually during the project. A number of manufacturing sites and suppliers were jointly evaluated by Bayer and GX Design Engineers.

### REGULATORY SUPPORT

GX Design Engineers remained involved right through the FDA approvals which took two years to complete.

### OPTRONICS

With a back to basics approach GX Design Engineers investigated and originated a number of techniques to determine the colour change of the 'dip and read' analysis strips. A number of 'Bread board' test beds were built initially. Eventually the team utilised CCD technology to read the strips and three patents have been awarded to GX Design Engineers for this invention (patent ownership resides with Bayer). GX Design Engineers optical designers created high efficiency light guides and complex lenses that fitted into a low cost but rigid injection moulded chassis. GX Design Engineers succeeded in utilising CCD technology to read immuno cartridges and were involved in the design of the cartridges as well.

### RAPID PROTOTYPING

Two ranges of initial working models were created. The first used rapid prototype techniques that established that the engineering principles were valid.

The second working models used injection moulded and metal cast (semi production) components so the accurate performance of the instrument could be ratified in clinical trials. Fifty of the units were built and were fully functional.

### VALUE ENGINEERING

Throughout the development GX Design Engineers researched, identified and utilised ultra low cost components. For example the LCD was originally a basic line 40 character display, the printer was a low cost Seiko device which found its way to production and rubber keymat technology was employed. The loading tray for the strips was manually operated to minimise costs.



### DID YOU KNOW?


THE BAYER CLINITEK STATUS IS IN USE IN OVER 100 COUNTRIES AROUND THE WORLD MAKING IT THE WIDEST USED DIAGNOSTIC TOOL CURRENTLY IN PRODUCTION.

### OUR SERVICES


-  ELECTRONICS
-  VALUE ENGINEERING
-  SOFTWARE DESIGN
-  REGULATORY SUPPORT
-  RAPID PROTOTYPING
-  OPTRONICS
-  MECHANICAL ENGINEERING
-  INDUSTRIAL DESIGN




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PRODUCT DESIGN



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